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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,576

03/19/2004

Jan Weber

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27774 7590 05/13/2009

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EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3774

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DELIVERY MODE

05/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/805,576	<b>Applicant(s)</b> WEBER ET AL.	
	<b>Examiner</b> Alvin J. Stewart	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-35 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) 2,8,14 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7, 9-13, 15-31, 33-35 and 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Arguments***

Applicant's arguments filed 02/23/09 have been fully considered but they are not persuasive.

The applicant representative discloses that the Examiner has not met his burden of establishing a prima facie case of obviousness. To establish a prima facie case of obviousness, three basic criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure.

1) criteria number one: the combination of Pacetti et al with the Sheu et al reference meet the first basic criteria. Sheu et al clearly discloses, in col. 1, lines 19-27; col. 2, lines 55-57; col. 4, lines 27-33; col. 7, lines 11-16, lines 28-33; and lines 40-514, lines 34-37, the motivation of having an elongated slot (see Figs. 6 and 7). Sheu clearly discloses that this hydrophilic material can be used in different substrates such as prosthetic or implants for the purpose of having resistance to pH changes, mechanical stress, absorption control, etc.. (see col. 3, lines 21-25 and col. 8, lines 31-38). Additionally, it is well known in the art to use polyelectrolytes in stents. For example, see US 6,245,579 B1, US 6,127,448, US 6,309,660; especially, US 6,451,871 disclosing that the term "biomedical device" can mean stents (see col. 4, lines 1-3).

2) criteria number two: the above combination would have a reasonable expectation of success because the Sheu reference clearly disclose that the layer of polyelectrolytes can be used in implant and it is well known in the art to have layers made of polyelectrolytes.

3) criteria number three: as mentioned in the rejection above the Pacetti et al reference clearly disclosed all the structure limitations except for the layers of polyelectrolytes shown in the Sheu et al reference.

For the above reasons the Examiner believes that the combinations of the prior art are proper.

Pacetti et al clearly discloses a metallic stent having a plurality of depressions covered with a plurality of polymeric layers that biodegrade when the coating is in contact with the patient's blood and having therapeutic agents disposed within the depression beneath the multilayer coating region.

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Sheu discloses an implant having a substrate made of metal, ceramic, etc..(see col. 2, lines 55-57 & col. 4, lines 27-33) covered by a polymeric layer having polyelectrolytes that are biodegradable.

Therefore, the Examiner is combining these two references (Pacetti & Sheu) in order to replace the bioabsorbable polymeric layer of the Pacetti reference with the polyelectrolyte layer of the Sheu reference in order to have resistance to pH changes, mechanical stress, absorption control, etc.. (see col. 3, lines 21-25 and col. 8, lines 31-38). Additionally, it is well known in the art to use polyelectrolytes in stents.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-7, 9, 10, 11, 20-30, 33-34 and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al US Patent 6,663,662 B2 in view of Sheu et al US Patent 5,837,377 A.

Pacetti et al discloses a stent comprising a metallic region whose surface comprises a plurality of depressions (24), a multilayer coating region of multiple polymeric layers (28, see col. 17, lines 65-67 and col. 18, lines 1-9; col. 18, lines 58-67; and col. 19, lines 15-28) deposited over the surface and a therapeutic agent disposed beneath or within the layers. However, Pacetti et al does not disclose a polyelectrolyte layers covering a stent.

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Sheu et al teaches a medical platform having a plurality of polyelectrolyte layers for the purpose of having water soluble biocompatible polymers covering a medical device (see col. 1, lines 19-27). Additionally, Sheu et al teaches a plurality of polyelectrolyte layers capable of having different layers with different net charges opposite in sign from the adjacent layers (see col. 7, lines 11-16; lines 28-33; and lines 40-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material property of the polymeric cover of the Pacetti et al reference with the water soluble multiple polymeric polyelectrolyte layers having different net charges in order to create a more versatile, biocompatible surface capable of being absorbed by water and for the purpose of having resistance to pH changes, mechanical stress, absorption control.

Claims 12, 13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al US Patent 6,663,662 B2 in view of Sheu et al US Patent 5,837,377 A and Amon et al US Patent 5,735,896.

Pacetti et al in view of Sheu disclose the invention substantially as claimed. However, Pacetti et al does not disclose a stent made of a ceramic surface.

Amon et al teaches a stent made of metal or ceramic for the purpose of expanding an occluded blood vessel (see col. 1, lines 11-15).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Pacetti et al reference by having a stent made of ceramic

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material in order to promote the biocompatibility of the implant and try to avoid any rejection by the body.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al US Patent 6,663,662 B2 in view of Sheu et al US Patent 5,837,377 A and further in view of Anderson et al US Patent pub. 2005/0172852 A1.

Pacetti et al as modify by Sheu et al disclose all the structure limitations as claimed. However, Pacetti et al does not disclose a polyelectrolyte coating having metal oxide nanoparticles.

Anderson et al discloses a coating of metal oxide particles for the purpose of having a porous surface (see paragraph 29).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Pacetti et al reference with the Anderson et al reference in order to create a porous surface.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al US Patent 6,506,437 B1 in view of Sheu et al US Patent 5,837,377 A.

Harish et al discloses the method of making a stent comprising a metallic region whose surface comprises a plurality of depressions (24), a layer coating region deposited over a surface of a stent and a therapeutic agent disposed beneath or within the layers (see Figs. 1 and 4A-4D; see col. 8 through col. 12). However, Pacetti et al does not disclose a polyelectrolyte layers covering a stent.

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Sheu et al teaches a medical platform having a plurality of polyelectrolyte layers for the purpose of having water soluble biocompatible polymers covering a medical device (see col. 1, lines 19-27). Additionally, Sheu et al teaches a plurality of polyelectrolyte layers capable of having different layers with different net charges opposite in sign from the adjacent layers (see col. 7, lines 11-16; lines 28-33; and lines 40-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the step of making the stent of the Harish et al reference with the water soluble multiple polymeric polyelectrolyte layers having different net charges in order to create a more versatile, biocompatible surface capable of being absorbed by water.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774

05/11/09